

Food and Drug Administration  
Hannover, MD 20795  
**RECEIVED***This is an untitled letter from  
FDA -*

APR 10 1997

JAN 2 57

LAW DEPARTMENT

Monica Krieger, Ph.D.  
CellPro, Incorporated  
22215 26<sup>th</sup> Avenue SE  
Bothell, Washington 98021

*Rick suggested everyone  
have a copy so we  
understand the level  
of scrutiny we are  
(under.)*  
*Monica*

Dear Dr. Krieger:

We are in receipt of a holiday greeting card that was disseminated by your company during the month of December, 1996. A copy is enclosed. Appearing on the back cover of the card is information about the artist which contains facts and efficacy claims related to a new indication for use of your CEPRATE® SC Stem Cell Concentration System for which a supplemental application has not been approved. As described in the conditions for approval of this device, no advertisement or other descriptive printed material issued by you or a distributor shall recommend or imply that the device may be utilized for uses that are not included in the FDA approved labeling.

The CEPRATE® SC Stem Cell Concentration System, manufactured by CellPro, Inc., is considered to be a device within the meaning of section 201(h) of the Federal Food Drug and Cosmetic Act (the Act). This device was approved for sale and distribution as a restricted device under the Premarket Approval (PMA) process described in section 515(d)(1)(B)(ii) of the Act for the following indication [Reference PMA Number BP940001]:

"...for the processing of autologous bone marrow to obtain a CD34+ cell enriched population which is intended for hematopoietic support after myeloablative chemotherapy."

The specific areas of concern related to the promotion of this device are noted below.

APR 29 '97 12:49

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- a. In your "about the artist" profile, a brief discussion regarding the use of the CEPRATE system in allogeneic stem cell transplants appears in the second paragraph.

The evaluation of stem cell transplants from allogeneic donors (e.g. use of stem cells from parents who are half-matched at tissue type antigens) is still experimental. Thus far, the Center for Biologics Evaluation and Research (CBER) has not received data from you that would render conclusive evidence to base your claim for use of the device in allogeneic transplants thereby expanding the donor pool and providing many more children with curative treatment of high risk leukemia. The new indication for use of this device described above may not be promoted until a PMA Supplement has been submitted and approved.

- b. In the third paragraph of the "about the artist" profile, the following claim is made: "Selecting stem cells reduces the chances of severe graft-versus-host disease that would otherwise occur if a child were to receive a half-matched bone marrow transplant from a parent"

CBER has not received a supplement to your PMA providing the clinical data that would provide the evidence needed to support this claim. In the absence of this information, one cannot conclude that CEPRATE®-selected (T- cell depleted) allogeneic transplants will prevent graft-versus-host disease or otherwise confer a benefit to the patient.

The above mentioned misrepresentations or like misrepresentations about the CellPro CEPRATE® device misbrand your product under Section 502(o) in that you have failed to comply with Section 515 of the Act. Section 515 of the Act requires that you file a PMA Supplement in accordance with the provisions described in 21 CFR Part 814.39. This regulation requires that an applicant submit a PMA Supplement before making a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA. We have determined the aforementioned claims regarding the CEPRATE® system affect both the safety and

efficacy of this device and, therefore, require the submission of a supplement that would provide the definitive evidence to support such claims.

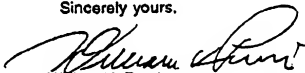
In addition, as a restricted device, you are further misbranding your device under Section 502(q)(1) of the Act, by including uses and claims in your advertising for this device that are regarded to be false and misleading.

It is your responsibility to ensure that the violations noted in this letter that may appear in other advertising or promotional materials are also corrected. You should take prompt action to correct the violations noted and assure compliance with the applicable regulations.

Please respond to this staff, in writing, within 15 days of the receipt of this letter. Your response should include the steps you plan on taking to remedy the above noted observations. Please send your response to the attention of:

Ms. Toni M. Stifano  
Center for Biologics Evaluation and Research  
Advertising and Promotional Labeling Staff, HFM-202  
1401 Rockville Pike  
Rockville, MD 20852-1448

Sincerely yours,



William V. Purvis  
Director, Advertising and Promotional  
Labeling Staff  
Center for Biologics Evaluation  
and Research

Enclosure



Thomson's first major medical success came in 1911, when he performed the first successful bone marrow transplant. He had been told that the only way to cure a child with leukemia was to give them a bone marrow transplant. At the time, this was considered a desperate measure, but Thomson was determined to try. He found a donor whose bone marrow was compatible with the child's, and he performed the transplant. The child survived, and Thomson's reputation as a pioneer in bone marrow transplantation grew.

Thomson's next major medical success came in 1913, when he performed the first successful kidney transplant. He had been told that the only way to cure a child with kidney failure was to give them a kidney transplant. At the time, this was considered a desperate measure, but Thomson was determined to try. He found a donor whose kidney was compatible with the child's, and he performed the transplant. The child survived, and Thomson's reputation as a pioneer in kidney transplantation grew.

Thomson's third major medical success came in 1915, when he performed the first successful heart transplant. He had been told that the only way to cure a child with heart failure was to give them a heart transplant. At the time, this was considered a desperate measure, but Thomson was determined to try. He found a donor whose heart was compatible with the child's, and he performed the transplant. The child survived, and Thomson's reputation as a pioneer in heart transplantation grew.

Thomson's fourth major medical success came in 1917, when he performed the first successful liver transplant. He had been told that the only way to cure a child with liver failure was to give them a liver transplant. At the time, this was considered a desperate measure, but Thomson was determined to try. He found a donor whose liver was compatible with the child's, and he performed the transplant. The child survived, and Thomson's reputation as a pioneer in liver transplantation grew.

